PE 12-3103







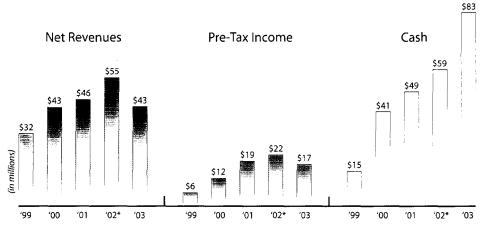
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# Noven Financial Highlights

STATEMENT OF OPERATIONS DATA:	2003	2002	2001	2000	1999
(unaudited) (in thousands, except per share amounts)					<del></del>
Net revenues	\$ 43,166	\$ 55,372	\$ 45,947	\$ 42,924	\$ 31,650
Cost of products sold	19,482	22,973	20,376	19,219	12,721
Research and development	8,082	11,634	10,973	13,621	7,171
Marketing, general and administrative	15,858	14,257	11,554	8,737	7,860
Total expenses	43,422	48,864	42,903	41,577	27,752
(Loss) income from operations	(256)	6,508	3,044	1,347	3,898
Equity in earnings of Novogyne	17,094	14,368	14,013	9,294	1,487
Interest income, net	659	822	1,770	1,385	343
Income before income taxes	17,497	21,698	18,827	12,026	5,728
Income tax expense (benefit)	6,301	7,819	6,736	(7,608)	(4,732)
Net income	\$ 11,196	\$ 13,879	\$ 12,091	\$ 19,634	\$ 10,460
Basic earnings per share	\$ 0.50	\$ 0.62	\$ 0.54	\$ 0.90	\$ 0.49
Diluted earnings per share	\$ 0.49	\$ 0.60	\$ 0.51	\$ 0.84	\$ 0.48
BALANCE SHEET DATA:					
Cash and cash equivalents	\$ 83,381	\$ 58,684	\$ 49,389	\$ 40,976	\$ 15,338
Total assets	169,484	137,702	136,228	104,031	56,888
Long-term notes payable	-	5	13	265	604
Deferred license revenue	50,005	29,445	32,758	27,109	8,028
Stockholders' equity	108,823	96,741	81,898	65,277	39,393

The financial data presented above is derived from the audited financial statements of Noven and should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the Financial Statements and related notes appearing in Noven's Form 10-K for the year ended December 31, 2003 filed with the SEC.



\* Publication of Women's Health Initiative Study (July 2002)

# about Noven

Noven Pharmaceuticals, Inc. (Nasdag: NOVN), headquartered in Miami, Florida, is a leading developer of advanced transdermal drug delivery technologies and prescription transdermal products. Our principal growth strategy is to apply our patented DOT Matrix® transdermal technology across diverse therapeutic categories with strong industry partners. Our patches are sold in over 30 countries, and a range of new prescription patches are under development. Together with Novartis Pharmaceuticals Corporation, we own Novogyne Pharmaceuticals, a successful women's health products company with net sales of over \$100 million in 2003. Novogyne's lead product is Vivelle Dot® (estradiol transdermal system) - the smallest estrogen patch in the world and the most dispensed estrogen patch in the U.S. With the most advanced transdermal technology on the market, we are committed to expanding the universe of transdermal therapies for the benefit of patients, industry partners and shareholders.

## OUR COLLABORATIONS

#### **Endo Pharmaceuticals**

#### Pain Management

Endo Pharmaceuticals Inc., a leader in pain management, has licensed our fentanyl patch for chronic pain. The patch is intended to be a generic version of Johnson & Johnson's Duragesic® (fentanyl transdermal system), and an application to market that patch is under review at the FDA. We are also working with Endo to develop new prescription patches that could extend our collaboration well beyond fentanyl.



#### P&G Pharmaceuticals

#### HSDD

We are developing new prescription patches for P&G Pharmaceuticals (P&GP), the pharmaceutical unit of The Procter & Gamble Company. We are exploring follow-on product opportunities for Intrinsa™, P&GP's in-licensed investigational testosterone patch designed to help restore desire in menopausal women who have Hypoactive Sexual Desire Disorder (HSDD).



#### Shire Pharmaceuticals

#### ADHD

Shire Pharmaceuticals Group plc, the market share leader in Attention Deficit Hyperactivity Disorder (ADHD) therapy, has licensed our MethyPatch® methylphenidate system. We are working with Shire to address issues raised in an FDA not approvable letter, and additional clinical studies are expected. If approved, MethyPatch would provide Shire with a valuable entry in the ADHD therapy market.



#### Novartis/Novogyne

#### Hormone Therapy

Menopausal hormone therapy (HT) was the commercial proving ground for our patented DOT Matrix patch technology. Our principal HT partners are Novartis Pharmaceuticals Corporation (our Novogyne joint venture partner) in the U.S. and Novartis Pharma AG abroad. Our HT business continues to represent an important source of profits and funding as we diversify our business into new therapeutic categories.





Robert C. Strauss

President, Chief Executive Officer & Chairman

# To Noven Shareholders:

Noven's strategy is to build shareholder value by commercializing our patented DOT Matrix and other patch technologies across diverse markets with strong

partners. From that standpoint, 2003 was a very successful year and one that helped establish a solid foundation for future growth.

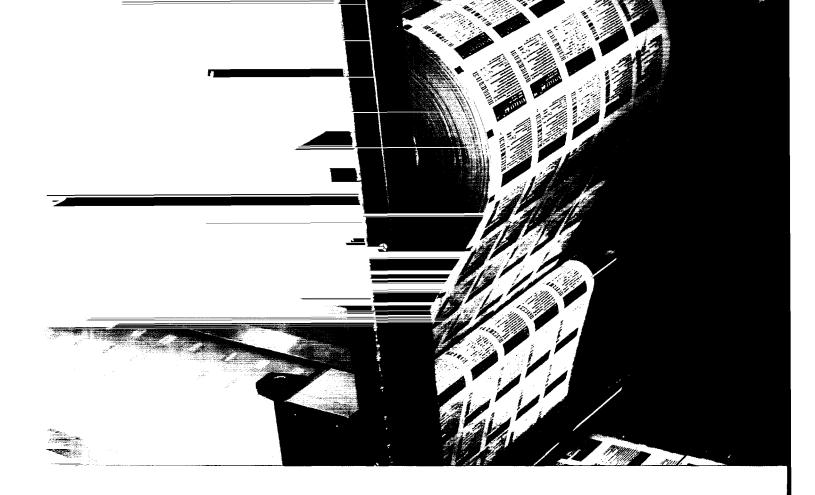
The year also presented challenges – the results of the Women's Health Initiative (WHI) study continued to impact our menopausal hormone therapy (HT) business, and an important developmental product (MethyPatch) received a not approvable

letter from the Food & Drug Administration (FDA). On balance, I believe we enter 2004 with a host of opportunities and with greater prospects for long-term growth than at any time in Noven's history.

#### New Collaborations

Since the beginning of 2003, we have established new collaborations that position the DOT Matrix platform as a central technology in the development programs of three leading companies:

• Shire Pharmaceuticals, the market share leader in Attention Deficit Hyperactivity Disorder (ADHD), chose our MethyPatch



transdermal methylphenidate system to attempt to pioneer the market for transdermal ADHD therapy. Currently, all ADHD medications are delivered orally.

- P&G Pharmaceuticals, the pharmaceutical unit of The Procter & Gamble Company, engaged us to develop prescription patches for Hypoactive Sexual Desire Disorder (HSDD), a therapeutic category with significant commercial potential.
   P&GP has recently initiated studies of our first collaborative product in humans.
- In early 2004, Endo Pharmaceuticals, a leader in pain management therapy, licensed our developmental fentanyl patch for chronic pain and partnered with us to develop new prescription patches. We hope to build a successful and productive collaboration with Endo that extends well beyond fentanyl and expands the universe of prescription patches.

Add to these new collaborations our existing alliances in HT with Novartis affiliates, and Noven now serves as transdermal developer for four companies in four therapeutic categories. In 2004, we will be working to advance these and possibly other collaborations that could drive substantial growth in 2005 and thereafter.

#### Menopausal Hormone Therapy

Along with progress, 2003 also offered challenges. The WHI study results, originally released in July of 2002, continued to impact HT. Since WHI, the overall HT market has declined, but our advanced patches have significantly outperformed their respective market segments.

In 2003, the U.S. HT market decreased 30% compared to the prior year. For the same period, total prescriptions for Novogyne's products decreased just 5.5% in the aggregate, and prescriptions for Vivelle Dot increased 9%. In fact, Vivelle Dot – the flagship



product for our DOT Matrix technology – was the only major estrogen therapy (ET) product to show an increase in total prescriptions during 2003.

We remain committed to HT. For 2004, I expect that our core HT business will remain very profitable and an important source of cash flow as we move to a more diversified business model. Longer term, I believe growth is possible for our HT business. The oral and transdermal ET markets in the U.S. continue to represent a market opportunity of well over \$1.0 billion. Vivelle Dot is now the number two ET product in the country behind only the oral product Premarin® (conjugated estrogen tablets). As the number two product in the category, we believe that we are the first prescription product considered by many physicians and patients seeking alternatives to oral Premarin.





New Additions: James W. Harris, Jr., PhD (left) joins Noven as VP – Quality Assurance & Quality Control, and Eduardo G. Abrao, M.D., PhD joins as VP – Clinical Development & Chief Medical Officer.

#### MethyPatch

In early 2003, Shire Pharmaceuticals licensed our MethyPatch transdermal methylphenidate system for ADHD. In exchange for global rights to the product, Shire paid \$25 million up front, and agreed to pay up to an additional \$125 million upon the attainment of certain milestones. Both companies were surprised and disappointed when we received a not approvable letter from the FDA. Noven and Shire are currently working to address the issues raised in the FDA letter. We are in dialogue with the FDA regarding our clinical strategy, and we plan to undertake additional studies that we believe are necessary to gain approval. Noven will fund the studies and Shire will conduct them. Our costs incurred in seeking approval will be offset dollar-for-dollar against a portion of the \$25 million previously received from Shire and deferred. This will reduce the impact of these costs on our net income.

Together with Shire, we remain committed to advancing MethyPatch through the regulatory process. The path to approval remains challenging, but the outcome holds significant reward. For patients, a valuable new therapy for ADHD may become available. Shire may gain a differentiated product in the methylphenidate market segment. And for Noven, milestones of up to \$125 million remain to be earned if the product is approved and successfully commercialized by Shire.

#### Inside Noven

The composition of Noven's board of directors is changing in 2004. Two new directors have joined us, and two have decided not to stand for re-election at the 2004 annual meeting. Joining us are Robert Savage and Donald Denkhaus. Bob has served almost 30 years in the pharmaceutical industry, and Don has over 30 years of broad-based business and accounting experience. Leaving us are Professor Regina Herzlinger and Lawrence DuBow. Both have cited personal reasons for their decision and both plan to continue to serve as directors until the May meeting. On behalf of Noven, I thank Regi and Laurie for many years of service

and counsel, and welcome the pharmaceutical and financial experience that our new directors bring to the Noven board.

We also recently added two members to Noven's senior management team. James Harris, Jr., PhD is now Noven's Vice President – Quality Assurance & Quality Control, and Eduardo Abrao, M.D., PhD is now our Vice President – Clinical Development & Chief Medical Officer. Each has already begun to make important contributions to our success as we seek to move Noven products through clinical trials, into production, and ultimately into the hands of patients.

#### More to Come

The industry alliances formed in the past twelve months and the new products that may emerge from them could drive substantial growth beginning as early as January 2005 (assuming our fentanyl patch is approved by that time). Alone, any one of these collaborations could significantly increase our revenues. Taken together, the potential for growth becomes even more substantial, and our position of leadership in transdermal drug delivery becomes even more established.

We continue with a focused program to identify and establish additional collaborations that we expect will further diversify our business. Our activity level in this area remains high, and I am confident that we will be successful in adding alliances that may enhance our growth prospects. If we are successful in establishing new collaborations and commercializing new products, revenues could increase in future years from a variety of sources, including the accumulated effect of up-front development payments, milestones earned over the course of development, royalties earned from product sales, profit sharing arrangements and/or ongoing manufacturing fees.

#### The Future

We enter 2004 in a position of strength. We have state-of-the-art transdermal drug delivery technology and a profitable HT busi-

ness that generates cash and helps fund our development pipeline. We have collaborations with four industry partners in diverse therapeutic categories, and we have good prospects for additional alliances. We have two products pending at the FDA, others in clinical trials, and more than 30 compounds that we believe we can deliver through our transdermal platforms.

With all of these attributes, plus a solid balance sheet, no long-term debt and over \$83 million in cash, it is fair to say that opportunities abound for our company. In that spirit, we entitled this annual report "Seize the Patch Opportunity." We intend that message to have different meanings for different audiences. If you are a Noven employee, it is a simple statement of our shared mandate to lead the industry in the development of new prescription patches. If you are a patient, it is a suggestion to discuss with your physician the possible benefits of patch therapy. If you represent a pharmaceutical company that is seeking transdermal capabilities, it is a reminder that there is no better place to look for a patch development partner. And if you are an investor or a member of the financial community, it is an invitation to join us as we move toward what I expect will be the most successful and rewarding period in Noven's history.

With sincere appreciation for your interest and support,

Robert C. Strauss

President, Chief Executive Officer & Chairman

April 2, 2004

▼ SEIZE THE PATCH OPPORTUNITY







Diane M. Barrett

Vice President & Chief Financial Officer

# From the CFO

2003 Financial Review

The discontinuation of the combination HT arm of the Women's Health Initiative (WHI) study in July 2002 had a profound impact on the global HT

industry. Our business, although down compared to 2002, did not decrease nearly as much as the industry, thanks in part to the performance of our Vivelle Dot estrogen patch.

For full-year 2003, we reported net revenues of \$43.2 million compared to \$55.4 million in 2002. The decline primarily reflects lower unit sales of our HT products as a continuing result of WHI, as well as the establishment of reserves for product recalls in the second half of the year.

In 2003, our research and development expense decreased 31% to \$8.1 million, reflecting the completion of significant methylphenidate and fentanyl clinical studies in 2002. We expect our investment in R&D to increase in 2004 compared to 2003 levels. New products are central to our growth strategy, and we plan to continue to conduct early-stage human clinical trials on prescription patches in our pipeline. Data from these trials can help attract collaboration partners, who would then generally fund the more expensive later-stage trials as part of a development or license agreement.

We recognized \$17.1 million in earnings from Novogyne, a 19% increase over 2002. Novogyne is our women's health products company owned jointly with Novartis Pharmaceuticals Corporation. Noven's net income was \$11.2 million, or \$0.49 per diluted share, compared to \$13.9 million, or \$0.60 per diluted share in 2002.

#### Novogyne

At \$101.1 million, Novogyne's 2003 net sales were 1% lower than in 2002. This slight decline reflected lower unit sales of Vivelle® patches (the original estradiol transdermal system) and CombiPatch® (estradiol/norethindrone transdermal system), partially offset by increased Vivelle Dot sales. The increase in Vivelle Dot sales in 2003 includes a customary price increase early in the year and higher unit sales. Novogyne's net sales benefited from an \$8.7 million decline in sales allowances and returns, primarily reflecting a \$15.2 million reduction in sales allowances and returns for expiring product,

partially offset by a \$6.5 million increase in allowances for recall-related returns. During 2003, Novogyne reduced trade inventories of Vivelle patches from elevated 2002 levels, and returns and sales volume for that product had declined substantially, permitting Novogyne to reduce its reserve for expiring product.

Novogyne's gross profit for the year was \$79.6 million – a gross margin of 79% in 2003 compared to 74% in 2002. This improvement was primarily due to lower sales allowances and returns, which increased net revenues without affecting cost of goods sold, and lower reserves for inventory obsolescence.

Novogyne's SG&A expense declined 7% to \$30.7 million, primarily due to lower promotional spending for CombiPatch, as well as expense reductions associated with the co-promotion of Novartis' Famvir® product. We continue to explore co-promotion or similar arrangements to better leverage the Novogyne sales force. As a result of these factors, 2003 net income at Novogyne increased 15% to \$42.9 million.

#### Cash

At December 31, 2003, we had \$83.4 million in cash and no long-term debt. In early 2004, we received an additional \$8.0 million payment as part of the Endo collaboration. Net cash provided by operating activities in 2003 primarily resulted from a \$25.0 million payment received from Shire on closing of the MethyPatch product license, and \$21.7 million in distributions from Novogyne. We are fortunate to have a business that generates cash. Subject to identifying the right opportunity, we have the resources and flexibility to invest a portion of our available cash in technologies that could supplement our drug delivery capabilities and ultimately enhance shareholder value.

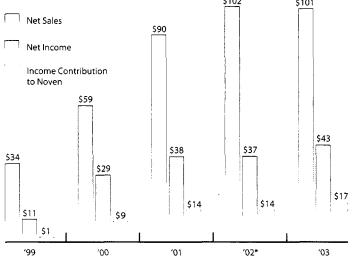


Diane M. Barrett

Vice President & Chief Financial Officer

April 2, 2004

# NOVOGYNE FINANCIAL RESULTS



\* Publication of Women's Health Initiative Study (July 2002)

Novogyne Pharmaceuticals, Noven's joint venture with Novartis Pharmaceuticals Corporation, had over \$100 million in net sales in each of the past two years.

We have the resources
and flexibility to invest in
technologies that could
supplement our drug
delivery capabilities and
ultimately enhance
shareholder value.



# Foundation

# DOT Matrix® Technology

Noven is built on the science and technology of delivering prescription medications through the skin. Our research and development team has developed and patented among the most technically advanced and broadly applicable transdermal drug delivery platforms in the pharmaceutical industry. Thirty U.S. patents and over 100 international patents protect our drug delivery technologies, and the key U.S. DOT Matrix patents do not begin to expire until 2014.

### Why a Patch?

Transdermal drug delivery can offer substantial benefits. Drug delivered through the skin avoids first pass liver metabolism, which frequently permits

the patch to put less drug in the system to obtain the same blood levels. For example, the most common estrogen pill puts over 13 times more estrogen into the body than a patch. Patches generally provide smoother, steadier blood levels. Compliance is often improved with patches because, while you can forget if you took your pill, you can always check to see if you are wearing your patch. Also, the duration of dosing can frequently be controlled by simply removing the patch.

#### Three Generations

Transdermal drug delivery can offer a range of therapeutic benefits, but historically it has been constrained by the wear and delivery limitations of early patch designs. In this area, Noven has created new opportunity and value with DOT Matrix technology.

DOT Matrix is a third generation diffusion-based patch technology that permits us to make patches that are

small, translucent, adherent and comfortable. These favorable wear characteristics present us with patch opportunities not generally available to prior generations of transdermals.

First generation transdermal patches generally use a reservoir system filled with drug mixed with an alcohol-based solution. In reservoir designs, the

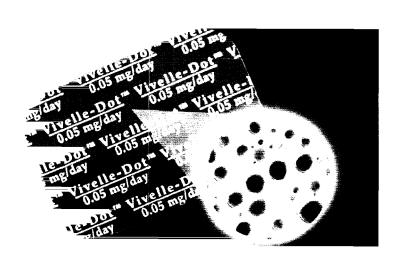
Thirty U.S. patents

protect our technologies,

and the key DOT Matrix

patents do not begin to

expire until 2014.



As illustrated in this electron microscope view of the surface of a Vivelle Dot patch, the adhesive layer of a DOT Matrix patch contains highly-concentrated drug cells surrounded by unimpaired silicone adhesive.

alcohol can irritate the skin and compromise adhesion. To keep the patch in place, a ring of adhesive often surrounds the active delivery area, which increases patch size. Because they hold a liquid or gel, reservoir patches are generally raised from the skin and can be punctured or could leak.

Second generation "drug-in-adhesive" patches generally have better wear characteristics than reservoir patches, but they too make compromises. In this design, the drug is usually mixed with an acrylic adhesive. The acrylic serves two roles – it holds the drug, and it holds the patch on the skin. A small patch needs high drug concentrations, but loading the acrylic with drug compromises its ability to stick. To address this, drug concentrations are kept relatively low, which dictates a greater patch area. The only choice to maintain a small size is to add a skin permeation enhancer, but then skin irritation issues can arise.

We do things differently. We hold patents on the use of two adhesives – an acrylic and a silicone. The acrylic serves only one purpose – to hold the drug. We load it with such high drug concentrations that it would never stick on its own. But we add a second, silicone adhesive to make the patch stick. The silicone essentially repels the drug/acrylic blend like oil in water. This forms microscopic, concentrated drug cells dispersed through the silicone adhesive. The high diffusion gradient between each drug cell and the skin causes the drug to penetrate the skin with great efficiency. The uncompromised silicone keeps the patch in place through exercise, swimming and high activity. By adjusting the ratios of drug, acrylic and silicone, we can adjust the delivery profile to meet the needs of a range of therapies.

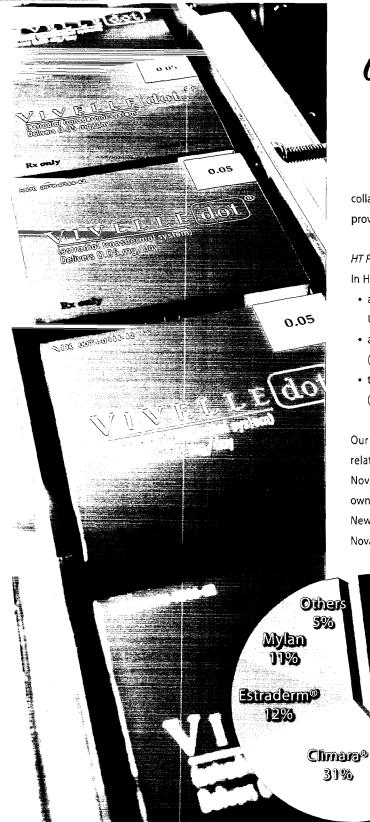
#### Small Size/More Molecules

The high-efficiency of DOT Matrix technology does more than allow us to make discreet, comfortable patches. It permits us to deliver two drugs in a patch that is smaller than many of our competitors' single drug patches. It also lets us make patch versions of drugs that otherwise would not fit into a commercially acceptable patch size. So, as we have increased efficiency and decreased patch size, we have increased the universe of molecules available to us, and gained access to commercially significant patch markets that others may be unable to enter.

# DOT MATRIX ADVANTAGE Listed Patches Deliver Same Daily Dose of Estrogen

Poduct  Patch Ace	Estradiol %
Vivelle Dot 9 5.0 cm²  Vivelle 9 14.5 cm²  Glimara 9 12.5 cm²  Estraderm 9 18.0 cm²	0.8 mg 22.4% 4.5 mg 4.0% 3.9 mg 90% 4.0 mg 4.4%
And the subminimum of the confidence of the conf	And the state of t
Mylan generic) 23.7 cm <sup>2</sup> Esclim <sup>2</sup> 22.0 cm <sup>2</sup> Alore 18.0 cm <sup>2</sup> *7-day patch others are 35	19 mg 18.0% 100 mg 18% 15 mg 116%

Noven's DOT Matrix technology helps make Vivelle Dot the most efficient estrogen patch on the market.



# Commercialization

# HORMONE THERAPY

We built our current business on prescription patches for menopausal hormone therapy (HT). HT was (and remains) the focus of our first significant

collaboration with an industry partner – Novartis. It was also the commercial proving ground for our patented DOT Matrix transdermal technology.

#### HT Products & Partners

In HT, Noven developed and manufactures three main products:

- an estrogen patch that uses our original patch technology (Vivelle in the U.S. and Menorest in most territories abroad);
- a state-of-the-art estrogen patch using DOT Matrix technology (Vivelle Dot in the U.S. and Estradot® in most territories abroad); and
- the first combination estrogen/progestin patch approved in the U.S. (CombiPatch in the U.S. and Estalis® abroad).

Our HT collaboration with Novartis is comprised of two distinct business relationships. Within the U.S., our products are marketed and sold by Novogyne Pharmaceuticals, a women's health products company jointly owned by Noven and Novartis Pharmaceuticals Corporation of East Hanover, New Jersey. Outside the U.S., our HT products are generally licensed to Novartis Pharma AG of Basel, Switzerland.

### What We Achieved

Vivelle

Product

Family

41%

Our HT business is an excellent example of what our technology can achieve in a therapeutic category. During the five-year period from 1998 to 2002, with only our HT patches on the market, our revenues increased from \$22 million to \$55 million; our \$4 million pre-tax loss became a \$22 million pre-tax profit; and our cash position increased almost ten fold from \$6 million to \$59

Noven's Vivelle product family is the most dispensed estrogen patch family in the U.S., holding a 41% share of total prescriptions as of February 2004.

million. In the process, we helped build a \$100 million business at Novogyne, and introduced patients and physicians to Vivelle Dot – the smallest and most advanced estrogen patch ever made.

Largely due to the release of the WHI study in July 2002, results from our HT business declined in 2003, but the sales performance of Vivelle Dot helped mitigate the impact of WHI on our business. In fact, Novogyne's net revenues in 2003 were just slightly below 2002 levels, and Novogyne contributed over \$17 million to Noven's 2003 income.

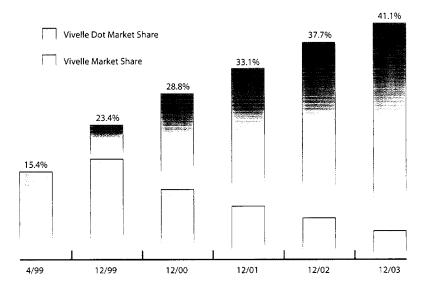
Just as our performance in HT demonstrated that a high-growth business can be built around our technology, the sales performance of Vivelle Dot proved what our patches can achieve in a competitive market.

Vivelle Dot was launched in 1999 into an established U.S. market that included some very good estrogen patches. Within three years, the Vivelle product family became the number one estrogen patch family in the U.S. Within four years, Vivelle Dot alone became the most dispensed estrogen patch in the U.S. Today, the Vivelle product family holds over 40% of the U.S. estrogen patch market, and Vivelle Dot is second only to Premarin in the entire estrogen therapy category. Premarin sales greatly exceed the sales of the entire ET patch market, so we believe Vivelle Dot still has considerable room to grow.

#### Success Breeds Success

The success of Vivelle Dot has not gone unnoticed in the pharmaceutical industry. It is one of the reasons that we have been able to attract industry partners in other therapeutic categories that may benefit from the introduction of transdermal medications. Noven's technology is now central to the transdermal development programs of four pharmaceutical companies, including the pharmaceutical unit of one of the largest consumer products companies in the world.

## VIVELLE FAMILY MARKET SHARE GROWTH



The Vivelle product family has gained significant share of the U.S. estrogen patch market each year since the launch of Vivelle Dot in April 1999.

The Vivelle product family holds over 40% of the U.S. estrogen patch market, and Vivelle Dot is second only to Premarin in the entire estrogen therapy category.

# Collaboration

In the past 12 months,
we have established
three new collaborations that should
advance our goal of
diversity and growth.

An important part of our strategy for consistent growth is to diversify our business beyond HT with industry partners capable of broadly commercializing our products. In the past 12 months, we have established three new development collaborations (Shire, P&G Pharmaceuticals and Endo) that should help advance our goal of diversity and growth.

## SHIRE PHARMACEUTICALS

In mid-2002, we filed a New Drug Application (NDA) with the FDA for MethyPatch®, a once-daily methylphenidate patch for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). MethyPatch combines methylphenidate, a benchmark ADHD therapy, with Noven's patented Dot Matrix transdermal technology.

#### ADHD

ADHD is the most commonly diagnosed and the most widely studied behavioral disorder in children in the U.S. It is characterized in part by developmentally inappropriate levels of attention, concentration and activity. Stimulant therapies, including methylphenidate and amphetamine-based products, are the most prescribed drug category for the treatment of ADHD.

Presently, all ADHD medications approved in the United States are delivered orally. The market is highly competitive, but we believe that our MethyPatch product, if approved, will be a valuable and differentiated ADHD therapy.

#### Global License

In the first half of 2003, we licensed the global rights to market the MethyPatch product to Shire Pharmaceuticals Group plc for payments of up to \$150 million and ongoing manufacturing revenues. We received \$25 million on closing of the license. Shire is a market leader in ADHD therapy, and its Adderall XR® product was one of the fastest growing ADHD therapies in 2003. MethyPatch, if approved, is expected to be Shire's entry into the methylphenidate market.

MethyPatch suffered a regulatory setback in April 2003 when we received a not approvable letter from the FDA relating to our pending NDA. A not

Noven's developmental MethyPatch product, licensed to Shire Pharmaceuticals, is intended to be a highly differentiated product in the market for ADHD therapies.



approvable letter is issued if the FDA does not consider an NDA approvable because of one or more deficiencies. The letter cited clinical and other issues as the basis for non-approval.

#### Addressing the Issues

We are working closely with Shire to address the clinical risk-benefit and other issues raised in the letter, and we expect to undertake additional MethyPatch product clinical studies in 2004. We will fund the additional studies and, given their extensive experience in this area, Shire will conduct them. Our costs incurred in pursuit of approval are expected to be netted against a portion of the \$25 million previously received from Shire and deferred. Therefore, these costs are not expected to impact Noven's 2004 research and development expenses. If the studies are successful, we expect to amend the NDA, which would be expected to initiate a six-month regulatory review period by the FDA.

# P&G PHARMACEUTICALS

In April of 2003, we established a development collaboration with P&G Pharmaceuticals, Inc. (P&GP), a subsidiary of The Procter & Gamble Company. In the first quarter of 2004, we announced that the patches under development explore follow-on product opportunities for P&GP's in-licensed investigational Intrinsa<sup>TM</sup> testosterone patch. The Intrinsa product is designed to help restore desire in menopausal women who have Hypoactive Sexual Desire Disorder (HSDD).

#### **HSDD**

HSDD is characterized by a lack of sexual desire, including a persistent or recurring deficiency or absence of sexual fantasies or thoughts or a lack of interest in sex. A recent study indicated that an estimated one in three surgically menopausal women in the U.S. has low sexual desire, and nearly half of these women report being distressed about it. Currently, there are no prescription medications approved by the FDA for the treatment of diminished sexual desire in women.



Noven is developing prescription patches to treat Hypoactive Sexual Desire Disorder for P&G Pharmaceuticals, a subsidiary of The Procter & Gamble Company.



If additional development efforts are successful, our collaboration with Endo could extend significantly beyond fentanyl.

Jeffrey F. Eisenberg, VP - Strategic Alliances & General Counsel, is team leader for Noven's developmental fentanyl patch project and part of Noven's integrated business development team.



#### Terms

Potential development milestones totaling \$4.8 million remain to be received by us under the P&GP collaboration, a portion of which is expected to be received in the remainder of 2004. Clinical studies and regulatory activities relating to the jointly developed products will be funded and managed by P&GP. P&GP has initiated human studies of the first product being developed under the collaboration. We expect to earn a royalty on product sales of collaborative products that reach market.

Previously, we had independently initiated human trials of a methyltestosterone patch for female sexual dysfunction, but we discontinued development in light of the P&GP collaboration.

## ENDO PHARMACEUTICALS

Our most recent industry collaboration marked our fourth industry partner and fourth therapeutic category. In February of 2004, we licensed the U.S. and Canadian rights to our developmental generic fentanyl patch to Endo Pharmaceuticals Inc. Our patch is intended to be the generic equivalent of Johnson & Johnson's Duragesic® (fentanyl transdermal system), which had branded U.S. sales of about \$1.3 billion in 2003. Our application to market the fentanyl patch is under review at the FDA. We believe that we are one of several companies developing a generic version of the Duragesic product.

#### Our Partner

Endo is an ideal partner to commercialize our fentanyl patch. They enjoy market leadership in pain management products and have excellent generic drug distribution capabilities. Their pain management franchise includes Lidoderm® (lidocaine patch 5%) and Percocet® (oxycodone and acetaminophen tablets). Strong growth in these product lines helped Endo's 2003 net sales to increase almost 50% to nearly \$600 million.

#### Terms

We received an \$8 million up-front payment on signing the agreement with Endo. Upon Endo's first commercial sale of the patch, we are entitled to receive an additional \$5 million to \$10 million, depending on the timing of

launch and the number of generic fentanyl competitors on the market. We will manufacture and supply the product at our cost and will share in Endo's profit from product sales.

#### Time to Market

Based on the current patent and exclusivity status of the Duragesic product, the earliest that our fentanyl patch could be launched is January 2005, assuming FDA approval is received by that time. If approved, the patch will compete against other generic versions of Duragesic.

In the market for generic products, time to market is critical – the first products launched typically achieve and maintain significant market share. To be prepared for a timely launch, we expect to manufacture launch supplies prior to receipt of FDA approval. This strategy is not without risk – if approval is not received or is delayed such that launch supplies are not saleable, we will share the manufacturing cost with Endo in accordance with an agreed upon formula.

#### International Opportunity

The Endo license covers only the U.S. and Canada. We retained rights to the fentanyl patch in all other territories, where the product has annual sales of several hundre'd million dollars. We are currently exploring strategies to commercialize the product in other territories as patents expire, which would geographically diversify our business.

#### Other Compounds

In addition to the fentanyl license, we have established a collaboration with Endo to identify and develop a number of new transdermal therapies. Of the \$8 million up-front payment, \$1.5 million will be allocated to fund feasibility studies undertaken by us to determine whether certain compounds identified by the parties can be delivered using our transdermal technology. Endo is expected to fund and manage clinical development of any compounds that proceed into clinical trials. If these development efforts are successful, our collaboration with Endo could extend significantly beyond transdermal fentanyl.



Noven has filed an application to market a generic version of Johnson & Johnson's Duragesic® (fentanyl transdermal system) for the management of chronic pain.

# Expectation

# NEW PRODUCTS & COLLABORATIONS

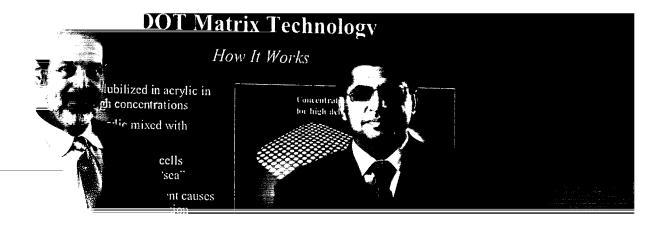
We believe that we are now the industry partner of choice for prescription transdermal drug development.

If our existing collaborations result in the successful commercialization of their target compounds, Noven stands to become a company many times larger than it is today. We are seeking, however, even greater opportunity. Our business development and technical teams are working to add new pipeline products and additional industry collaborations, each with the potential to add incremental growth to our business.

Research and development is critical to our business development efforts. Our ability to attract partners and structure collaborations on favorable economic terms is improved if we have early human clinical data in hand. Before partnering with Shire, P&GP and Endo, we had developed relevant clinical data. Accordingly, in 2004 and thereafter, we intend to conduct a range of early clinical studies that will let us demonstrate blood levels of new patch formulations. We expect that the more costly later-stage clinical programs generally will be funded and managed by partners.

# NOVEN'S TRANSDERMAL PRODUCT PIPELINE

	Compound	Indication	Pre-Clinical Clinicals Filed With FDA Marketed
	Estrogen	Menopause	
	Estrogen/Progestin	Menopause	Control Contro
	Fentanyl (Duragesic®)	Pain	Construction of the Constr
	Methylphenidate	ADHD	
	Next Gen. HT	Menopause	911
	P&GP (first)	HSDD	
	P&GP (other)	HSDD	
	Endo (multiple)	Undisclosed	
A Company of the Comp	Others available for collaborative development	Various	







# Expanding the Patch Universe

In the U.S., there are only about a dozen prescription compounds approved for delivery in a transdermal patch. Through feasibility testing and other analysis, we believe that our DOT Matrix platform is capable of delivering at least three times as many compounds as are currently approved in the U.S. (see table on page 18). This list represents a sampling of what our business development team presents to potential new partners. The list is not exhaustive, however, and does not include proprietary molecules that other pharmaceutical companies may bring to Noven for feasibility testing and transdermal development.

Our Dot Matrix patch technology is flexible enough to be useful for a range of compounds in many therapeutic categories, and this appeals to partners who take a therapeutic category approach to new product development. Juan Mantelle, VP & Chief Technical Officer (left), and Pavan Handa, VP – Business Development, present DOT Matrix technology to potential industry partners.



### EXPANDING THE PATCH UNIVERSE

#### ADHD Incontinence Methylphenidate Tolterodine Amphetamine Oxybutynin **Allergies Motion Sickness** Azelastine Scopolomine Alzheimer's Muscle Spasms **Tacrine** Cyclobenzaprine Anxiety Nausea Alprazolam Granisetron **Birth Control** Obesity **Various** Phentermine Estrogen/Progestin/ Methamphetamine Combinations Pain Depression Buprenorphine **Buspirone** Fentanyl Sufentanyl **Paroxetine** Levorphanol **Bupropion** Lidocaine Various NSAIDs Epilepsy Clonazepam **Triptans** Parkinson's **Hypertension** Enalapril Pergolide Ramipril Pramipexole Clonidine Ropinirole Timolol Rotigotine Hypogonadism/FSD Testosterone Through feasibility testing and/or other analysis, Noven believes the listed compounds can be delivered through its transdermal systems. See the table on page 16 for Noven's active development pipeline.

This is a relatively new capability in the industry. Before DOT Matrix, transdermal platforms were generally not flexible enough to permit a company to take a therapeutic category approach to transdermal drug development. We proved we could meet the needs of an entire category when we developed both an estrogen patch and a combination estrogen/progestin patch for HT years before anyone else. Similarly, with P&GP, we are focused on different compounds, each addressing HSDD. And while the additional compounds to be developed with Endo have yet to be selected and may not be limited to pain, we have no shortage of compounds for pain management that we believe we can deliver through DOT Matrix.

To maintain our leadership position in transdermal drug delivery, we are seeking innovative ways to improve and expand our technology. In this regard, we are continuously filing patent applications on patch technologies that may expand our capabilities beyond the DOT Matrix platform, possibly permitting delivery of larger molecules in higher doses. Our goal is to assure that, if anyone surpasses the DOT Matrix standard, it will be Noven.

#### The Preferred Choice

Our track record has caught the attention of a range of pharmaceutical companies. They saw our lead HT product enjoy success in an established U.S. estrogen patch market and perform well in the adverse conditions following WHI. They saw us pioneer the first two-drug patch in the U.S. They saw our technologies attract other industry leaders, including one of the world's largest consumer products companies. They understand that we can deliver a wide range of molecules in significant therapeutic categories.

As a result, we believe we are now the industry partner of choice for transdermal drug development, and we have earned that reputation on the basis of our science and the performance of our products. This reputation should serve us well as we seek to further diversify our business through new products and alliances, and as we advance our goal of leading the industry in the development of new prescription patches.  $\nabla$ 

# Financial and Other Information -









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NOVEN PHARMACEUTICALS, INC. STATEMENTS OF OPERATIONS Years Ended December 31,	2003	2002	2001
(unaudited) (in thousands, except per share amounts)			
Revenues: Product revenues – Novogyne:			
Product sales	\$ 15,932 4,978	\$ 25,394 4,505	\$ 16,689 4,037
Product revenues – Novogyne Product revenues – third parties	20,910 16,206	29,899 20,300	20,726 21,321
Total product revenues	37,116 6,050	50,199 5,173	42,047 3,900
Net revenues	43,166	55,372	45,947
Expenses:			
Cost of products sold	19,482	22,973	20,376
Research and development	8,082	11,634	10,973
Marketing, general and administrative	15,858	14,257	11,554
Total expenses	43,422	48,864	42,903
(Loss) income from operations	(256)	6,508	3,044
Equity in earnings of Novogyne	17,094	14,368	14,013
Interest income, net	659	822	1,770
Income before income taxes	17,497	21,698	18,827
Provision for income taxes	6,301	7,819	6,736
Net income	\$11,196	\$ 13,879	\$12,091
Basic earnings per share	\$ 0.50	\$ 0.62	\$ 0.54
Diluted earnings per share	\$ 0.49	\$ 0.60	\$ 0.51
Weighted average number of common shares outstanding:			
Basic	22,544	22,532	22,367
Diluted	22,989	23,321	23,511

#### Note to Noven's Selected Financial Information

The selected financial information presented above and on pages 21-23 of this report is derived from the audited financial statements of Noven and should be read in conjunction with the Financial Statements and related notes appearing in Noven's Form 10-K, filed with the SEC.

NOVEN PHARMACEUTICALS, INC. **BALANCE SHEETS** December 31, 2003 2002 (unaudited) (in thousands, except share data) **ASSETS** Current Assets: Cash and cash equivalents ..... \$ 83,381 \$ 58,684 Accounts receivable - trade (less allowance for doubtful accounts of \$84 in 2003 and \$79 in 2002)..... 4,359 3.809 6,320 2,581 Inventories ..... 5,200 5.613 6,500 2,600 Prepaid income taxes and other current assets..... 3,219 541 74,378 108,429 Property, plant and equipment, net ..... 18,354 16,232 Other Assets: Investment in Novogyne. 28,368 34,684 12,175 9,831 Net deferred income tax asset..... 1,977 1,996 Patent development costs, net ...... 181 581 42,701 47,092 \$137,702 \$169,484 LIABILITIES AND STOCKHOLDERS' EQUITY Current Liabilities: \$ 4,060 \$ 5,062 8 3,549 3,734 2,090 2,063 772 829 21,112 3,525 31,768 15,036 Long-Term Liabilities: 5 Notes payable ..... Deferred license revenues 28,893 25,920 60,661 40,961 Commitments and Contingencies Stockholders' Equity: Preferred stock – authorized 100,000 shares of \$.01 par value; Common stock – authorized 80,000,000 shares, par value \$.0001 per share; 2 2 79,244 78,358 Retained earnings..... 29,577 18,381 108,823 96,741 \$169,484 \$137,702 See Note to Noven's Selected Financial Information on page 20 of this report.



# NOVEN PHARMACEUTICALS, INC. STATEMENTS OF STOCKHOLDERS' EQUITY

V 5 1 15 1 6	0	0. 1		Additional	Retained Earnings/	
Years Ended December 31, 2003, 2002 and 2001	Shares	on Stock Am	ount	Paid-in Capital	(Accumulated Deficit)	Total
(unaudited) (in thousands)						<u>_</u>
Balance at December 31, 2000	22,178	\$	2	\$ 72,864	\$ (7,589)	\$ 65,277
to stock option plan, net	304		_	3,090	_	3,090
stock options	_		_	1,385	_	1,385
charitable organization	_		_	55 —	— 12,091	55 12,091
Balance at December 31, 2001	22,482		2	77,394	4,502	81,898
to stock option plan, net	97		<del></del>	771	_	771
stock options				153	_	153
charitable organization				40	_	40
Net income					13,879	13,879
Balance at December 31, 2002	22,579		2	78,358	18,381	96,741
to stock option plan, net	245		_	1,617	_	1,617
to outside directors  Tax benefit from exercise of	3		-	31		31
stock options	_			527	_	527
common stock	(105)		_	(1,289)	_	(1,289)
Net income					11,196	11,196
Balance at December 31, 2003	22,722	\$	2	\$ 79,244	\$ 29,577	\$ 108,823

See Note to Noven's Selected Financial Information on page 20 of this report.

NOVEN PHARMACEUTICALS, INC. STATEMENTS OF CASH FLOWS Years Ended December 31, (unaudited) (in thousands) 2003 2002 2001 Cash flows from operating activities: Net income..... \$13,879 \$12,091 \$11,196 Adjustments to reconcile net income to net cash provided by operating activities: 2,278 2,216 2,488 341 312 233 Amortization of non-competition agreement..... 400 400 233 Deferred income tax (benefit) expense...... (6,244)2,586 709 Expense related to issuance of shares of stock to outside directors and options to charitable organization..... 31 40 55 Recognition of deferred contract revenues..... (2,024)(1,787)(1,049)Recognition of deferred license revenues..... (4,026)(3,386)(2,851)(17,094)Equity in earnings of Novogyne.... (14,368)(14,013)21,739 11,727 13,081 Changes in operating assets and liabilities: 550 (3,051)4,369 (Increase) decrease in accounts receivable - Novogyne, net . . . . . . . (3.739)2,577 (2,241)1,774 Decrease (increase) in inventories...... 413 (1,289)(Increase) decrease in prepaid income taxes (480)(237)191 Decrease (increase) in deposits and other assets..... 26 (1,129)Decrease in accounts payable ..... (1,002)(558)(177)Increase (decrease) in accrued compensation 185 2.031 (986)27 (603)1,775 Increase in deferred contract revenue..... 1,967 1,199 1,630 8,500 Increase in deferred license revenue...... 25.000 73 Direct expenses incurred in pursuit of MethyPatch® regulatory approval. . . (414)Cash flows provided by operating activities ..... 29,104 11,787 24,683 Cash flows from investing activities: (3,033)(4,400)(2,749)(15,680)Contributions to Novogyne ..... (322)Payments for patent development costs..... (262)(307)(4,722)(3,011)(19,020)Cash flows from financing activities: 771 3,090 1 617 Purchase and retirement of common stock ...... (1,289)(13)(252)(340)Cash flows provided by financing activities..... 315 519 2,750 8,413 24,697 9,295 Cash and cash equivalents, beginning of year..... 49,389 40,976 58,684 Cash and cash equivalents, end of year ..... \$49,389 \$83,381 \$58,684

See Note to Noven's Selected Financial Information on page 20 of this report.



VIVELLE VENTURES LLC d/b/a NOVOGYNE PHARMACEUTICALS STATEMENTS OF OPERATIONS

Years Ended December 31, (unaudited)	2003	2002	2001
NET SALES	<del></del>		
Third parties	\$ 98,572,264	\$ 97,755,546	\$ 88,808,362
Novartis Pharmaceuticals Canada, Inc	2,505,148	4,729,216	1,149,817
	101,077,412	102,484,762	89,958,179
COST OF SALES			
Third parties	15,454,422	19,550,963	16,272,541
Noven royalties	4,978,247	4,504,663	4,036,972
Novartis Pharmaceuticals Canada, Inc.	1,052,221	2,079,829	523,358
	21,484,890	26,135,455	20,832,871
Gross profit	79,592,522	76,349,307	69,125,308
OPERATING EXPENSES			
Administrative expenses	2,652,908	2,195,203	1,926,320
Sales and marketing expenses	28,019,902	30,895,914	25,420,730
Amortization expense	6,179,465	6,179,465	4,634,598
Income from operations	42,740,247	37,078,725	37,143,660
OTHER INCOME			
Interest income	181,957	349,741	733,600
Net income	\$ 42,922,204	\$ 37,428,466	\$ 37,877,260

Note to Novogyne's Selected Financial Information

The selected financial information presented above and on pages 25-27 of this report is derived from the audited financial statements of Novogyne and should be read in conjunction with the Financial Statements and related notes appearing in Noven's Form 10-K, filed with the SEC.

VIVELLE VENTURES LLC
d/b/a NOVOGYNE PHARMACEUTICALS
BALANCE SHEETS

December 31, (unaudited)	2003	2002
ASSETS	·	
Current assets		
Due from Affiliate – Novartis Pharmaceuticals Corporation	\$ 21,332,627	\$ 28,470,812
Due from Novartis Pharmaceuticals Canada, Inc. Finished goods inventory (net of reserves of \$949,137 and \$975,624	696,620	_
as of December 31, 2003 and 2002)	2,682,113	6,315,282
Other current assets	265,521	41,390
Total current assets	24,976,881	34,827,484
Long-term assets (Note 3)	44,801,117	50,980,582
Total assets	\$ 69,777,998	\$ 85,808,066
LIABILITIES AND MEMBERS' CAPITAL		
Current liabilities		
Due to Affiliate – Noven Pharmaceuticals, Inc	\$ 7,164,624	\$ 4,565,279
Accrued liabilities	173,250	122,383
Allowance for returns (Note 4)	14,240,281	12,780,006
Total current liabilities	21,578,155	17,467,668
Commitments and contingencies (Note 7) Members' capital		
Capital contributions	32,857,909	32,857,909
Accumulated earnings	15,341,934	35,482,489
Total members' capital	48,199,843	68,340,398
Total liabilities and members' capital	\$ 69,777,998	\$ 85,808,066

See Note to Novogyne's Selected Financial Information on page 24 of this report.



## VIVELLE VENTURES LLC d/b/a NOVOGYNE PHARMACEUTICALS STATEMENTS OF MEMBERS' CAPITAL

Years Ended December 31, (unaudited)	TOTAL
MEMBERS' CAPITAL AT DECEMBER 31, 2000	\$ 31,425,906 37,877,260 (30,819,000)
Distributions to Noven  Capital contributions by Novartis.  Capital contributions by Noven	(13,081,000) 16,320,000 15,680,000
MEMBERS' CAPITAL AT DECEMBER 31, 2001	57,403,166
Net income	37,428,466 (14,763,251) (11,727,983)
MEMBERS' CAPITAL AT DECEMBER 31, 2002	68,340,398
Net income	42,922,204 (39,652,880) (23,409,879)
MEMBERS' CAPITAL AT DECEMBER 31, 2003	\$ 48,199,843

See Note to Novogyne's Selected Financial Information on page 24 of this report.

VIVELLE VENTURES LLC			
d/b/a NOVOGYNE PHARMACEUTICALS			
STATEMENTS OF CASH FLOWS Years Ended December 31, (unaudited)	2003	2002	2001
OPERATING ACTIVITIES			
Net income	\$ 42,922,204	\$ 37,428,466	\$ 37,877,260
Adjustments to reconcile net income to net cash			, ,
provided by operating activities			
Amortization of marketing rights	6,179,465	6,179,465	4,634,598
Obsolescence reserve	(26,487)	725,624	50,000
Changes in assets and liabilities, net of assets acquired			
Due from affiliate - Novartis Pharmaceuticals Corporation	7,138,185	(11,977,785)	19,486,451
Due from Novartis Pharmaceuticals Canada, Inc	(696,620)	876,263	(631,575)
Inventories	3,659,656	(1,064,501)	3,111,424
Other current assets	(224,131)	308,017	(349,407)
Due to affiliate - Noven Pharmaceuticals, Inc	2,599,345	(2,095,479)	2,188,408
Other liabilities	1,511,142	6,111,164	804,753
Net cash provided by operating activities	63,062,759	36,491,234	67,171,912
INVESTING ACTIVITIES			
Cash paid to purchase the Combipatch® marketing rights			
and inventory (Note 3)	_	(10,000,000)	(55,271,912)
Net cash provided by investing activities		(10,000,000)	(55,271,912)
FINANCING ACTIVITIES			
Contribution by members (Note 3)	_	_	32,000,000
Distributions to members (Note 5)	(63,062,759)	(26,491,234)	(43,900,000)
Net cash provided by financing activities	(63,062,759)	(26,491,234)	(11,900,000)
Net change in cash			_
CASH AND CASH EQUIVALENTS			
Beginning of year			
End of year	\$ —	\$ —	\$ —

See Note to Novogyne's Selected Financial Information on page 24 of this report.

#### FORWARD LOOKING STATEMENTS

Except for historical information, the matters discussed in this report contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 that involve substantial risks and uncertainties. In this report, the words "believe," "could", "expects", "hopes", "will", "may", "should" and similar expressions identify certain of such forward-looking statements. Actual results, performance or achievements could differ materially from those contemplated, expressed or implied by the forward-looking statements contained herein. These statements are based largely on the current expectations of Noven and are subject to risks and uncertainties that are subject to change based on factors which are, in many instances, beyond Noven's control, including risks and uncertainties associated with: HT Market, including any further impact on Noven's HT business including any arising from mandated product label changes or the announcement of additional negative clinical results or other reasons, which could reduce or eliminate any profit contribution by Novogyne to Noven and/or sales of HT products from Noven to Novartis Pharma AG; the risk that Novogyne may not be able to realize the full value of the marketing rights for CombiPatch; risks associated with increased competition in the HT market as a result of the launches of new dosage forms; the European HT market may be limited due to pricing pressures; Regulatory Matters, including actions that may be taken against Noven by the FDA or other regulators, whether relating to manufacturing processes, suppliers, commercialized products, products in development or otherwise, any related costs; the timing of any FDA approval, which is outside Noven's control and which may impact the success of product launch and market penetration; Production Matters, including the timing and magnitude of any product recalls; the impact of the recalls or related issues on Novartis' or other partners' strategy for the commercialization of Noven's products; the possibility that Noven's estimates of the impact of future returns and charges may prove inaccurate, incomplete or otherwise incorrect; the impact of detected or undetected product stability failures or other product defects on Noven's ability to estimate its reserves for sales returns and other associated accounting consequences; Noven's Partners, including the risk that Noven's development partners may have different or conflicting priorities than Noven's which may adversely impact their ability or willingness to assist in the development and commercialization of Noven's products; Noven's ability to attract additional development partners; the possibility that Noven's technologies may not be approvable or suitable for use in additional therapeutic categories, including those categories addressed through products developed with Noven's development partners; the possibility that Noven may be unsuccessful in achieving milestone objectives under its development programs and may not receive any further payments; the possibility that Noven's development programs may not proceed on schedule or as expected; the possibility that Noven's current development priorities could render it unable to advance its other development projects or increase the cost of advancing those projects; and risks related to Noven's dependence on Novartis to monitor trade inventory levels for Novogyne and to perform Novogyne's financial, accounting, inventory and sales deductions functions; MethyPatch, including the FDA's review of the proposed MethyPatch product protocol, including the risk that FDA may determine that proposed protocols and/or proposed clinical strategies are not acceptable or do not address FDA's concerns regarding approval of the MethyPatch product NDA; the possibility that additional MethyPatch product studies may not be commenced in a timely manner or at all due to FDA concerns or otherwise; Shire's control over the management of any additional MethyPatch product clinical trials, including the risk that Shire may elect to manage any such studies differently than Noven might have, incorrectly or inadequately; the possibility that any additional studies of MethyPatch will not produce results that support approval or that, even if the additional studies are completed and is successful, MethyPatch may not ultimately be approved or commercialized; the availability of non-stimulant or other once-daily ADHD therapies could negatively impact market penetration of MethyPatch; the possibility that the cost of any additional MethyPatch product study and related expenses may be higher than anticipated and may exceed the total amount of license revenues available to offset such costs and expenses; the possibility that Noven's method of accounting for the \$25 million received from Shire could change under certain circumstances, including if the parties' MethyPatch product strategy changes or if MethyPatch development is discontinued; the possibility that Noven's development strategy could change if Shire were to terminate the agreement under certain circumstances, or if MethyPatch product were not ultimately approved or were abandoned; Fentanyl Patch, including the risks and uncertainties associated with the FDA's review of Noven's fentanyl ANDA, the possibility that milestone payments may be reduced and/or Endo may exercise its contractual right to terminate the license agreement if the product launch is delayed for any reason, including delay in obtaining FDA approval; patent or other strategies by third parties could delay or prevent the launch of Noven's fentanyl patch or other products; the possibility that Noven may be unable to recover significant costs to manufacture fentanyl patches prior to product launch if FDA approval is not obtained on a timely basis or at all; the possibility that, even if approved, Noven's fentanyl patch or other products may not be successfully commercialized due to competitive market conditions or other factors, including physician/patient preferences for other therapies; Other Matters, including risks related to our reliance on suppliers for certain raw materials used in our products; expected fluctuations in quarterly revenues and research and development expenses; and Noven's success at managing the risks relating to the foregoing. In addition to the risks and factors identified above, reference is also made to the other risks and factors detailed in reports filed by Noven with the Securities and Exchange Commission. Noven cautions that the foregoing list of factors is not exhaustive.

## MARKET INFORMATION

Our Common Stock is listed on the Nasdaq Stock Market and is traded under the symbol NOVN. The following table sets forth, for the periods indicated, the high and low sale prices for the Common Stock as reported on the Nasdaq Stock Market.

_		High Price	Low Price
	First Quarter, 2003	\$14.69	\$ 7.30
	Second Quarter, 2003	14.98	8.10
	Third Quarter, 2003	12.64	9.96
	Fourth Quarter, 2003	15.80	9.69
	First Quarter, 2002	\$23.22	\$16.01
	Second Quarter, 2002	27.51	18.57
	Third Quarter, 2002	25.37	8.91
	Fourth Quarter, 2002	14.50	8.95

#### **HOLDERS**

As of March 1, 2004, we had 316 stockholders of record.

### DIVIDENDS

We have never paid a cash dividend on our Common Stock and do not anticipate paying cash dividends in the foreseeable future.

# The Moven Team



Robert C. Strauss President, CEO & Chairman

We would not be where we are today without the hard work and dedication of our more than 300 employees. About 190 individuals manufacture our patches and assure high quality in all of our products; over 30 are in research and development, clinical research and regulatory affairs; and over 80 are in marketing, administration and support. Women comprise about 55% of our workforce, and 65% represent minority groups. In addition to direct Noven employees, our Novogyne joint venture has a 120-person contract sales force that we manage as part of our responsibilities under the joint venture agreements with Novartis. We believe that the Novogyne sales force is one of the most effective and efficient specialty sales forces in the industry, and its track record with our prescription patch products supports that belief.



Eduardo G. Abrao, M.D., PhD VP - Clinical Development & Chief Medical Officer



Diane M. Barrett VP & Chief Financial Officer



Jeffrey F. Eisenberg VP - Strategic Alliances & General Counsel



W. Neil Jones VP - Marketing & Sales



Juan Mantelle VP & Chief Technical Officer



Carolyn Donaldson VP - Human Resources



Pavan Handa VP - Business Development



James W. Harris, Jr., PhD VP - Quality Assurance & Quality Control



Joseph C. Jones VP - Corporate Affairs



David Ovitt VP - Operations



#### **BOARD OF DIRECTORS**

#### **Robert C. Strauss**

President, Chief Executive Officer & Chairman of the Board Noven Pharmaceuticals, Inc.

#### Sidney Braginsky

President & Chief Executive Officer Atropos Technology Inc.

#### John G. Clarkson, M.D.

Professor & Senior Vice President for Medical Affairs & Dean University of Miami School of Medicine

#### Donald A. Denkhaus

Chairman of the Board TM Systems, LLC

#### Lawrence J. DuBow\*

Chairman of the Board HMS Sales and Marketing, Inc.

#### Regina E. Herzlinger\*

Professor of Business Administration Harvard Business School

#### Robert G. Savage

Worldwide Chairman, Pharmaceutical Group (Retired) Johnson & Johnson

## Wayne P. Yetter

Advisory Board Chairman Alterity Partners

#### **COMMITTEES OF THE BOARD**

#### **Audit Committee**

Regina E. Herzlinger (Chairperson)\* Sidney Braginsky Donald A. Denkhaus Lawrence J. DuBow\* Wayne P. Yetter

#### **Compensation & Stock Option Committee**

John G. Clarkson, M.D. (Chairperson)
Sidney Braginsky
Lawrence J. DuBow\*

#### **Nominating & Corporate Governance Committee**

Wayne P. Yetter (Chairperson) Regina E. Herzlinger\* John G. Clarkson, M.D.

#### S.E.C. FORM 10-K

Noven's 2003 Annual Report on Form 10-K, which is incorporated herein by reference, is available free of charge by writing to:

Joseph C. Jones Vice President – Corporate Affairs Noven Pharmaceuticals, Inc. 11960 S.W. 144th Street Miami, Florida 33186

#### **ANNUAL MEETING**

Noven's annual meeting of stockholders will be held on May 18, 2004, at 10:00 a.m. at Noven's headquarters, located at 11960 SW 144th Street, Miami, FL 33186.

#### TRANSFER AGENT AND REGISTRAR

American Stock Transfer and Trust Company 59 Maiden Lane New York, New York 10038 Attn: Paula Caroppoli

#### **INDEPENDENT AUDITORS**

Deloitte & Touche LLP 200 South Biscayne Boulevard Suite 400 Miami, Florida 33131-2310

## TRADEMARKS

MethyPatch and DOT Matrix are among the trademarks or registered trademarks owned by Noven Pharmaceuticals, Inc. All other brand and product names are or may be trademarks of, and are used to identify products or services of, their respective owners.

<sup>\*</sup> Not standing for reelection at the 2004 annual meeting of stockholders.

Noven Pharmaceuticals, Inc. ▼ 11960 S.W. 144th Street ▼ Miami, Florida 33186 ▼ www.noven.com